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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/21/2004

Jeremy Marshall

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466

7590

08/19/2008

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,513	Applicant(s) MARSHALL, JEREMY	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 12 and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by Morita (US 5,628,765). Morita discloses a lancet comprising a needle having a pointed tip, a support body (86) enclosing the needle (44) such that the pointed tip projects beyond the end of the support body, and a removable guard (84) located over the pointed tip of the needle, the guard having been integrally molded from plastics material with the support body and connected thereto by a breakable neck portion (90). The removable guard portion has an outer peripheral thickened region describing a generally U-shape or C-shape (see distal end of device in figs. 10 and 12), a central region of thinner section (area proximal of enlarged end and also within U-shape, which is thinner than thickened peripheral region) and a further thickened region encasing the tip of the needle (area of 84 just around tip). This region is being considered thickened compared to the neck region (90; see fig. 11). The ends of the peripheral thickened region are spaced from the region encasing the neck such that the ends are bridged to the

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region encasing the neck only by the thinner section. It is noted that the claim does not include the limitation that the thickened region encasing the tip of the needle is thickened compared to the thin central region. Therefore, the region encasing the needle can be considered thickened as it is thickened compared to neck region 90. The region of the guard just distal of the needle tip can be considered the thin central region as it is thinner than the peripheral thickened section.

4. Regarding claim 14, the guard can be considered tab-like with the thickened region forming arc-like portions on two sides of the guard which lead to the thinner section of the plastics material.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita in view of Crossman (GB 2,352,403). Morita discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point.

7. Crossman discloses that is well known to have a hole (8) formed in the distal end of a plastic injection-molded guard (figs. 1-3). Adding such a hole to the device of Morita would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard.

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8. **Claims 15 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morita in view of Higgins (US 3,358,689). Morita discloses a method of forming a lancet including using plastic injection molding process wherein a mold is constructed with cavities arranged to result in the structure of the lancet above (col. 7 ll. 23-29). In order to attain the structure of the lancet of Morita, it would have been obvious to construct the mold to have an outer peripheral thickened hollow region of generally u or c shape which leads to a thinner hollow section and a further enlarged hollow region encasing the needle spaced from the ends of the peripheral thickened hollow region to leave a gap therebetween that is bridged only by the thinner hollow section. Morita does not expressly disclose an entry point for the plastics material at an end remote from the needle point. However, Higgins discloses that it is well known to provide an entry point (88) in a lancet guard mold at an end of the guard remote from the pointed needle tip and it would have been obvious to provide such an entry point positioned in this manner on the mold of Morita as it provides a way of delivering the plastics material.

9. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita in view of Higgins as applied to claim 15 above, and further in view of Crossman (GB 2,352,403). Morita in view of Higgins discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point as well as a pin to cause the plastics material to flow around pin, thereby forming the hole.

10. Crossman discloses that is well known to have a hole (8) formed in the distal end of a guard (figs. 1-3). Adding such a hole to the device of Morita would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Crossman discloses that pins can be used to form holes in an injection molded plastics body (p. 3 ll. 7-9) and it would have been obvious to use such a pin to form the hole in the guard.

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11. **Claims 12, 14, 15, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin (US 6,168,606) in view of Higgins. Levin discloses a lancet comprising a needle having a pointed tip, a support body (41) enclosing the needle (46) such that the pointed tip projects beyond the end of the support body, and a removable guard (80, 90) located over the pointed tip of the needle, the guard having been integrally molded from plastics material with the support body and connected thereto by a breakable neck portion (110). The removable guard portion has an outer peripheral thickened region describing a generally U-shape or C-shape (90), a central region of thinner section (100; fig. 10) and a further thickened region encasing (80) the tip of the needle. The ends of the peripheral thickened region are spaced from the region encasing the neck such that a gap between the ends and the thickened region encasing the needle tip is bridged only by the thinner section (100). Although the shape of (90) is a disk, it is noted that a peripheral portion of 90 can be taken which is generally u or c shaped, u or c shape being thickener than the thin section (100). Regarding claim 14, the guard can be considered tab-like. As discussed above, when the peripheral portion of (90) is considered, it can be said to form arc-like portions on two side edges of the guard which lead to the thinner section (100). Levin discloses that the support body and neck are made of plastic but fails to disclose that the guard is made of plastics molded material.

12. Higgins discloses that it is old and well known in the art to integrally form a guard and support member with a breakable neck between them using a plastics-molded material because it is an economical manufacturing technique (see col. 1). It would have been obvious to one of ordinary skill in the art to modify the device of Levin to make the guard, support body, and breakable neck region out of plastics molded material so that the three members can be made integrally in an economical manner as made obvious by Higgins.

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13. Regarding the method of claim 15, Higgins teaches that it is old and well known to in the art to form a lancet using features of the mold to form the shape of the lancet. The needle is held in the mold as seen in fig. 12 and plastics material is injected into the mold via an entry point (88) to crease the guard about the needle tip (co. I. 4, II. 46-52). In order to make the lancet of Levin, it would have been obvious to form the mold with an outer edge thickened hollow region that leads to a thinner hollow section approaching the needle tip and a further enlarged hollow region about the needle tip since such shape a shape would result in the lancet of Levin as Higgins discloses that injecting plastic into an entry point forms a lancet shaped by the mold.

14. **Claims 13 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin in view of Higgins as applied to claims 12 and 15 above, and further in view of Crossman (GB 2,352,403). Levin in view of Higgins discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point as well as a pin to cause the plastics material to flow around pin, thereby forming the hole.

15. Crossman discloses that is well known to have a hole (8) formed in the distal end of a guard (figs. 1-3). Adding such a hole to the device of Levin would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Crossman discloses that pins can be used to form holes in an injection molded plastics body (p. 3 II. 7-9) and it would have been obvious to use such a pin to form the hole in the guard.

Response to Arguments

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments to the claims. In a

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previous office action mailed 7/12/2007, the examiner rejected claims 12 and 14 over Levin et al. (US 6,168,606) in view of Higgins (US 3,358,689) and later withdrew these rejections in the final action mailed 1/10/2008, in view of amendments made by applicant on 10/12/2007.

However, after further consideration, the examiner has again rejected claims 12 and 14 (additionally claims 15, 17) over Levin et al. in view of Higgins for the following reasons. A peripheral portion of tab (90) of Levin et al. can be assigned such that this peripheral portion has a u or c shape. This portion can be considered thickened with respect to thin section 100. There is a gap, which is between the ends of this u or c shape and the thickened region (80) encasing the needle tip, bridged only by the thinner section (100). As currently claimed, the peripheral portion is thickened with respect to the thin section and the thin section may fall anywhere between the peripheral portion and thickened region so that at least a portion of the length formed between these two portions (portion considered claimed "gap") are bridged only by a thinner section. It is noted that a peripheral portion does not have to include the entire periphery of the guard.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 8/13/2008

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731